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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/535,687

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EXAMINER

FERNANDEZ, SUSAN EMILY

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/535,687	Applicant(s) KNOWLES ET AL.	
	Examiner SUSAN E. FERNANDEZ	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-11 and 13-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-11 and 13-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The amendment filed April 8, 2008, has been received and entered.

Claims 3, 4, and 12 have been cancelled.

Claims 1, 2, 5-11, and 13-20 are pending and examined on the merits.

Information Disclosure Statement

The information disclosure statement filed May 19, 2005, fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 5-11, and 13-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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Claim 1 recites that the reaction mixture "includes an ionic buffer" wherein the transport of the ionic buffer is prevented, which is considered new matter. Though the specification teaches that when a reaction mixture includes a cationic buffer, the transport of the cationic buffer is prevented according to the claimed process (page 8, lines 30 through page 9, line 3), no indication is provided that such is the case if an anionic buffer is included in the reaction mixture. Rather, the specification indicates that "However, if a standard anionic buffer system is being used in the separation system, the buffer is progressively displaced and pH control cannot be maintained" (page 9, lines 29-32).

Additionally, the disclosure lacks support for the recitation that the separation membrane is "...of a polarity to prevent transport of the ionic buffer." There is no indication in the specification that the polarity of the separation membrane has a role in ionic buffer transport.

Because the specification as filed fails to provide clear support for the new claim language, a new matter rejection is clearly proper for claim 1 and its dependent claims (1, 2, 5-11, 13-20: note that claim 8 is being examined as a process according to claim 1 for the reasons discussed below).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8 and 17-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 8 is indefinite since it depends from claim 4, a cancelled claim. For examination purposes, claim 8 will be read as a process according to claim 1. If depending from claim 1, the recitation “the bipolar ion exchange membrane” in the second line of the claim lacks antecedent basis as there is no mention of a “bipolar ion exchange membrane” in claim 1. Thus, claims 8 and 17-19 are rejected under 35 U.S.C. 112, second paragraph.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 5-9, 13, 14, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB 1217035 in view of Xu (Desalination. 2001. 140: 247-258. Listed on IDS) and Egen et al. (US 5,336,387), and in light of Mani (US 6,110,342).

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GB '035 discloses "...a method of controlling the oxidation of a carbohydrate or polyhydric alcohol comprising treating a feedstock containing the carbohydrate or polyhydric alcohol with an oxidizing agent to form a reaction mixture containing a monocarboxylic acid; and removing the monocarboxylic acid during formation thereof so that the feedstock is maintained in the reaction mixture at a concentration greater than that of the monocarboxylic acid" (page 1, lines 76-87). Moreover, such a process is taught for the preparation of lactic acid by fermentation (page 3 lines 60-74). The process may be carried out by using electrochemical oxidation in an electrolyzer (page 2, lines 37-40), and the oxidizing agents may be enzymes or bacteria (page 2, lines 41-44). Figure 2 shows an embodiment of the invention. The reaction mixture is sent into a reactor vessel wherein an anion exchange membrane (2) separates the reaction mixture from the cathode (4), and a cation exchange membrane (3) separates the reaction mixture from the anode (5) wherein the electrodes apply an electric field (page 3, lines 90-95). Clearly the electrodes do not come into contact with the reaction mixture, as they are separated by separation membranes. Figure 2 also demonstrates that the electric field applied is a direct current (DC) field. Thus, claims 1-4, 6, 13, and 14 are anticipated. Claim 7 is also anticipated given the teachings at lines 108-113 on page 3.

GB '035 does not expressly disclose that a bipolar ion exchange membrane is used as the ion exchange membranes used in the device for practicing the GB '035 invention.

Xu discloses the advantages of using a bipolar ion exchange membrane in electrolysis processes, pointing out that its use results in lower energy consumption, and that since it does not generate gases from electrodialytic water splitting, there is no corrosion to both cathode and anode (page 247, second column). Moreover, Xu points out that "bipolar membrane water

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splitting technology provides an ideal complement to the fermentation technology by removing the product acid while simultaneously providing an equivalent amount of base for use in adjusting the pH in the fermentor" (page 253, first column, last paragraph).

At the time the invention was made, the person of ordinary skill in the art would have been motivated to have used a bipolar ion exchange membrane in the electrolyzer utilized for performing the GB '035 invention. One of ordinary skill in the art would have been motivated to do this given that it lowers energy consumption, avoids electrode corrosion, and removes the product acid (monocarboxylic acid).

Further still, GB '035 does not expressly disclose that the reaction mixture comprises a cationic buffer system with an organic product forming an anionic component.

Egen et al. discloses that a buffer comprising tris is a suitable buffer for an electrodialysis system (column 19, lines 19-23).

At the time the invention was made, it would have been obvious to the person of ordinary skill in the art to have used a tris buffer, which is a cationic buffer, in the process of GB '035 wherein an electrolyzer is used. One of ordinary skill in the art would have been motivated to do this since the person of ordinary skill in the art would have recognized the suitability of using a tris buffer in any electrodialysis system.

Finally, the above references do not expressly disclose that the transport of the cationic buffer is prevented. Nevertheless, the Mani patent, drawn to an electrodialysis device, points out that "A bipolar membrane is a membrane which splits water and prevents the passage of both anions and cations" (column 1, lines 39-41). Therefore, in practicing the GB '035 invention with

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a bipolar membrane and a cationic buffer, the transport of the cationic buffer is prevented given that cation passage is prevented.

A holding of obviousness is clearly required.

Claims 1, 2, 5-11, and 13-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB 1217035 ("GB '035"), Xu, Egen et al., and Mani as applied to claims 1, 2, 5-9, 13, 14, and 17 above, and further in view of Hongo et al. (Applied and Environmental Microbiology. 1986. 52(2): 314-319) and Nomura et al. (Biotechnology and Bioengineering. 1987. 30: 788-793).

As discussed above, GB '035, Xu, Egen et al., and Mani render claims 1, 2, 5-9, 13, 14, and 17 obvious. However, these references do not expressly disclose that the DC electric field applied is adjusted to control the pH of the reaction mixture.

Hongo et al. discloses an electrodialysis fermentation process wherein fermentation broth is passed into an electrodialyzer for the removal of produced lactic acid (abstract and page 315, first column). The pH of the reaction mixture is monitored, and when the pH falls below the set pH value, the direct-current power supply connected to a pH controller is operated to cause a flow of electric current which then results in an increase in pH (page 315, first column, last paragraph through page 315, second column, first paragraph).

At the time the invention was made, the person of ordinary skill in the art would have been motivated to have adjusted the DC electric field to control the pH of the reaction mixture of the GB '035 invention. One of ordinary skill in the art would have been motivated to do this since DC electric field is shown to be suitable for the adjustment of the pH of a reaction mixture

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in an electrodialysis system. Moreover, it would have been particularly suitable for maintaining the pH of a reaction mixture for the production of lactic acid, which is disclosed as Example 3 of GB '035 (page 5, line 125 through page 6, line 71). In controlling the DC electric field, it would have been obvious to have used a computer program since such a program would be necessary for the operation of the pH controller (programming necessary for adjusting the DC electric field according to the detected pH).

The references also differ from the claimed invention in that they do not expressly disclose that immobilized cultures are used in the GB '035 process.

Nomura et al. discloses immobilized growing bacterial cells entrapped in calcium alginate for use in lactic acid production occurring in an electrodialysis system (page 788, second column, second paragraph). The immobilization of cells resolves problems occurring when free microbial cells are used: "...microbial cells in the fermentation broth gradually attach to the anion-exchange membranes, causing an increase in electric resistance and a decrease in the efficiency of electrodialysis" (page 788, first column, last sentence through second column, first paragraph).

At the time the invention was made, it would have been obvious to the person of ordinary skill in the art to have used immobilized growing bacterial cells entrapped in calcium alginate as the bacterial culture for performing the GB '035 invention. One of ordinary skill in the art would have been motivated to do this in order to have prevented the attachment of microbial cells to the anion-exchange membrane, which would have caused an increase in electric resistance and a decrease in the electrodialysis efficiency.

Thus, a holding of obviousness is clearly required.

Response to Arguments

Applicant's arguments filed April 8, 2008, have been fully considered but they are not persuasive. The applicant argues that the argument that the person or ordinary skill in the art would have recognized the suitability of using a tris buffer in any electrodialysis system fails to identify any reason to combine references. However, it is a matter of combining prior art elements according to known methods to yield predictable results. The tris buffer is a known buffer for an electrodialysis system, so it would have yielded the predictable result of electrodialysis in the methods rendered obvious by GB '035 and Xu. Moreover, KSR forecloses the argument that a specific teaching, suggestion, or motivation is required to support a finding of obviousness. See *Ex parte Smith*, --USPQ2d--, slip op. at 20, (Bd. Pat. App. & Interf. June 25, 2007). Further still, the claims do not require that the loss of buffer is prevented in order to control the pH by adjusting the applied current.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN E. FERNANDEZ whose telephone number is (571)272-3444. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford/
Primary Examiner, Art Unit 1651

Susan E. Fernandez
Examiner
Art Unit 1651

sef